

IN THE CLAIMS

This listing of claims will replace all prior versions and listing of claims in the application. The following amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

Claims 1 – 218. (Cancelled).

Claim 219. (Withdrawn) A solid oral dosage form, comprising:

(a) at least one proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole and pantoprazole, or an enantiomer, isomer, prodrug, free base, or salt thereof wherein at least some of the proton pump inhibitor is not enteric coated;

(b) a buffering agent comprising sodium bicarbonate; and

(c) one or more optional excipients;

wherein upon oral administration of the solid oral dosage form to a subject, the subject exhibits a T_{\max} of said proton pump inhibitor within about 1 hour after administration.

Claim 220. (Withdrawn) The solid oral dosage form of claim 219, wherein the buffering agent is present in an amount sufficient to preserve the ability of at least some of the proton pump inhibitor to elicit a therapeutic effect.

Claim 221. (Withdrawn) The solid oral dosage form of claim 219, wherein the buffering agent is present in an amount sufficient to increase the pH of the stomach contents of a subject to a pH that prevents or inhibits acid degradation of at least some of the proton pump inhibitor.

Claim 222. (Withdrawn) The solid oral dosage form of claim 219, wherein the buffering agent is present in a total amount of about 3 mEq to about 45 mEq.

Claim 223. (Withdrawn) The solid oral dosage form of claim 219, wherein the buffering agent is present in a total amount of at least about 3 mEq.

Claim 224. (Withdrawn) The solid oral dosage form of claim 219, wherein the sodium bicarbonate is present in an amount of about 250 mg to about 4000 mg.

Claim 225. (Withdrawn) The solid oral dosage form of claim 219, wherein the sodium bicarbonate is present in an amount of about 4 mEq to about 30 mEq.

Claim 226. (Withdrawn) The solid oral dosage form of claim 219, wherein the buffering agent further comprises a buffering agent selected from the group consisting of potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, aluminum hydroxide, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum magnesium hydroxide, sodium citrate, sodium tartarate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, sodium acetate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, and calcium gluconate, calcium bicarbonate, calcium citrate, sodium phosphate, or mixtures thereof.

Claim 227. (Withdrawn) The solid oral dosage form of claim 219, wherein the buffering agent further comprises a buffering agent selected from the group consisting of magnesium hydroxide, magnesium oxide, potassium carbonate, sodium carbonate, calcium carbonate, calcium bicarbonate, or mixtures thereof.

Claim 228. (Withdrawn) The solid oral dosage form of claim 219, wherein the buffering agent further comprises a buffering agent selected from the group consisting of sodium carbonate or calcium carbonate.

Claim 229. (Withdrawn) The solid oral dosage form of claim 219, wherein the buffering agent further comprises magnesium hydroxide.

Claim 230. (Withdrawn) The solid oral dosage form of claim 219, wherein the solid oral dosage form is selected from the group consisting of a tablet, a capsule, a pellet, a granule, or a troche.

Claim 231. (Withdrawn) The solid oral dosage form of claim 219, wherein the solid oral dosage form is a tablet.

Claim 232. (Withdrawn) The solid oral dosage form of claim 231, wherein the tablet is a chewable tablet.

Claim 233. (Withdrawn) The solid oral dosage form of claim 219, wherein the solid oral dosage form is a capsule.

Claim 234. (Withdrawn) The solid oral dosage form of claim 219, wherein the proton pump inhibitor is present in an amount of about 10 mg to about 100 mg.

Claim 235. (Withdrawn) The solid oral dosage form of claim 219, wherein the proton pump inhibitor is present in an amount of about 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, or 60 mg.

Claim 236. (Withdrawn) The solid oral dosage form of claim 219, wherein the proton pump inhibitor is omeprazole or an enantiomer, isomer, free base, salt, or mixture thereof.

Claim 237. (Withdrawn) The solid oral dosage form of claim 219, wherein the proton pump inhibitor is lansoprazole or an enantiomer, isomer, free base, salt, or mixture thereof.

Claim 238. (Withdrawn) The solid oral dosage form of claim 219, wherein the proton pump inhibitor is esomeprazole or an enantiomer, isomer, free base salt, or mixture thereof.

Claim 239. (Withdrawn) The solid oral dosage form of claim 219, wherein the excipient comprises a binder.

Claim 240. (Withdrawn) The solid oral dosage form of claim 239, wherein the binder is hydroxypropylmethylcellulose.

Claim 241. (Withdrawn) The solid oral dosage form of claim 219, wherein the excipient comprises a flavoring agent.

Claim 242. (Withdrawn) The solid oral dosage form of claim 219, wherein the excipient comprises a disintegrant.

Claim 243. (Withdrawn) The solid oral dosage form of claim 242, wherein the dosage form is a capsule.

Claim 244. (Withdrawn) The solid oral dosage form of claim 242, wherein the excipient comprises a lubricant.

Claim 245. (Withdrawn) The solid oral dosage form of claim 242, wherein the proton pump inhibitor is micronized.

Claim 246. (Withdrawn) The solid oral dosage form of claim 219, wherein at least some of the proton pump inhibitor is enteric coated.

Claim 247. (Withdrawn) The solid oral dosage form of claim 219, wherein within 5 minutes after administration of the solid oral dosage form to the subject, the pH of the subject's stomach is equal to or greater than the essential pH of the proton pump inhibitor.

Claim 248. (Withdrawn) The solid oral dosage form of claim 219, wherein upon administration of the solid oral dosage form to the subject, the subject exhibits a T_{max} within about 45 minutes after administration.

Claim 249. (Withdrawn) The solid oral dosage form of claim 219, wherein upon administration of the solid oral dosage form to the subject, the subject exhibits an average plasma concentration of at least about 1.0 µg/ml at any time within about 40 minutes after administration.

Claim 250. (Withdrawn) The solid oral dosage form of claim 219, wherein upon administration of the solid oral dosage form to the subject, the subject exhibits an average plasma concentration of at least about 0.1 µg/ml at any time within about 15 minutes after administration.

Claim 251. (Withdrawn) A method of administering a proton pump inhibitor to a subject, comprising the steps of:

- (a) providing a solid oral dosage form, comprising:
 - (i) at least one proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole and pantoprazole, or an enantiomer, isomer, free base, salt, or mixture thereof wherein at least some of the proton pump inhibitor is not enteric coated;
 - (ii) at least one buffering agent wherein the buffering agent is present in an amount sufficient to increase the pH of the stomach contents of a subject to a pH that prevents or inhibits acid degradation of at least some of the proton pump inhibitor; and
 - (iii) one or more optional excipients; and
- (b) orally administering the solid oral dosage form to the subject;

wherein upon oral administration of the solid oral dosage form to a subject, the subject exhibits a T_{\max} of the proton pump inhibitor within about 1 hour after administration; and

wherein the method does not include administration of a poly[phosphoryl/sulfon]-ated carbohydrate to the subject.

Claim 252. (Withdrawn) The method of claim 251, wherein the proton pump inhibitor is present in an amount of about 10 mg to about 100 mg.

Claim 253. (Withdrawn) The method of claim 251, wherein the proton pump inhibitor is present in an amount of about 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, or 60 mg.

Claim 254. (Withdrawn) The method of claim 251, wherein the proton pump inhibitor is omeprazole or an enantiomer, isomer, free base, salt, or mixture thereof.

Claim 255. (Withdrawn) The method of claim 251, wherein the proton pump inhibitor is lansoprazole or an enantiomer, isomer, free base, salt, or mixture thereof.

Claim 256. (Withdrawn) The method of claim 251, wherein the proton pump inhibitor is esomeprazole or an enantiomer, isomer, free base salt, or mixture thereof.

Claim 257. (Withdrawn) The method of claim 251, wherein the solid oral dosage form further comprises a binder.

Claim 258. (Withdrawn) The method of claim 251, wherein the solid oral dosage form further comprises a flavoring agent.

Claim 259. (Withdrawn) The method of claim 251, wherein the solid oral dosage form further comprises a disintegrant.

Claim 260. (Withdrawn) The method of claim 251, wherein the buffering agent is selected from the group consisting of sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, aluminum hydroxide, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum magnesium hydroxide, sodium citrate, sodium tartarate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate,

tripotassium phosphate, sodium acetate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, and calcium gluconate, calcium bicarbonate, calcium citrate, sodium phosphate, or mixtures thereof.

Claim 261. (Withdrawn) The method of claim 251, wherein the buffering agent is present in a total amount of about 3 mEq to about 45 mEq.

Claim 262. (Withdrawn) The method of claim 251, wherein the buffering agent is present in a total amount of at least about 3 mEq.

Claim 263. (Withdrawn) The method of claim 251, wherein the buffering agent comprises sodium bicarbonate in an amount of about 250 mg to about 4000 mgs.

Claim 264. (Withdrawn) The method of claim 251, wherein the buffering agent is selected from the group consisting of sodium bicarbonate, sodium carbonate, calcium carbonate, magnesium hydroxide, or mixtures thereof.

Claim 265. (Withdrawn) The method of claim 261, wherein the proton pump inhibitor is micronized.

Claim 266. (Withdrawn) The method of claim 261, wherein the solid oral dosage form is selected from the group consisting of a tablet, a capsule, a powder, a pellet, a granule, or a troche.

Claim 267. (Withdrawn) The method of claim 266, wherein the solid oral dosage form is a tablet.

Claim 268. (Withdrawn) The method of claim 266, wherein the solid oral dosage form is a capsule.

Claim 269. (Withdrawn) The method of claim 267, wherein the tablet is a chewable tablet.

Claim 270. (Withdrawn) The method of claim 251, wherein within 5 minutes after administration of the solid oral dosage form to the subject, the pH of the subject's stomach is equal to or greater than the essential pH of the proton pump inhibitor.

Claim 271. (Withdrawn) The method of claim 251, wherein upon administration of the solid oral dosage form to the subject, the subject exhibits an average plasma concentration of at least about 1.0 µg/ml at any time within about 40 minutes after administration.

Claim 272. (Withdrawn) The method of claim 251, wherein upon administration of the solid oral dosage form to the subject, the subject exhibits an average plasma concentration of at least about 0.1 µg/ml at any time within about 15 minutes after administration.

Claim 273. (New) A pharmaceutical composition, comprising: about 5 mg to about 100 mg non-enteric coated omeprazole or an isomer, tautomer, free base, or salt thereof, sodium bicarbonate in an amount of about 0.2 mEq to 5 mEq per 2 mg of omeprazole, and at least one thickening agent, wherein the composition is in a form of a powder for suspension that is storage stable at room temperature.

Claim 274. (New) The composition of claim 273, wherein the omeprazole is present in the composition in an amount of about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35, about 40 mg, about 45, about 50 mg, about 55, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, or about 100 mg.

Claim 275. (New) The composition of claim 273, wherein the sodium bicarbonate is present in the composition in a total amount of about 7 mEq to about 25 mEq.

Claim 276. (New) The composition of claim 273, wherein the sodium bicarbonate is present in the composition in a total amount of about 10 mEq.

Claim 277. (New) The composition of claim 273, wherein the sodium bicarbonate is present in the composition in a total amount of about 20 mEq.

Claim 278. (New) The composition of claim 273, wherein the sodium bicarbonate is present in the composition in a total amount of about 40 mEq.

Claim 279. (New) The composition of claim 273, wherein the sodium bicarbonate is present in the composition in a total amount of about 250 mg to about 4000 mg.

Claim 280. (New) The composition of claim 273, wherein the sodium bicarbonate is present in the composition in a total amount of about 1000 mg to about 1680 mg.

Claim 281. (New) The composition of claim 277, wherein the omeprazole is present in the composition in an amount of about 20 mg.

Claim 282. (New) The composition of claim 277, wherein the omeprazole is present in the composition in an amount of about 40 mg.

Claim 283. (New) The composition of claim 273, wherein the composition comprises magnesium hydroxide.

Claim 284. (New) The composition of claim 283, wherein the magnesium hydroxide is present in the composition in a total amount of about 12 mEq to about 24 mEq.

Claim 285. (New) The composition of claim 273, wherein at least a portion of the omeprazole is micronized.

Claim 286. (New) The composition of claim 273, wherein at least a portion of the sodium bicarbonate is micronized.

Claim 287. (New) The composition of claim 280, wherein the omeprazole is present in the composition in an amount of about 20 mg.

Claim 288. (New) The composition of claim 280, wherein the omeprazole is present in the composition in an amount of about 40 mg.

Claim 289. (New) The composition of claim 287, wherein after mixing the powder in water to form a suspension, the concentration of sodium bicarbonate ranges from approximately 5 percent to approximately 60 percent.

Claim 290. (New) The composition of claim 273, wherein after mixing the powder for suspension in water, the concentration of sodium bicarbonate is approximately 5 percent.

Claim 291. (New) The composition of claim 273, wherein after mixing the powder for suspension in water, the concentration of sodium bicarbonate ranges from approximately 7.5 percent to approximately 10 percent.

Claim 292. (New) The composition of claim 273, wherein after mixing the powder in water to form a suspension, the concentration of sodium bicarbonate ranges is approximately 8.4 percent.

Claim 293. (New) The composition of claim 273, wherein after mixing the powder in water to form a suspension, the concentration of sodium bicarbonate ranges is approximately 10 percent.

Claim 294. (New) A pharmaceutical composition, comprising: about 20-mg to about 40 mg non-enteric coated omeprazole or an isomer, tautomer, free base, or salt thereof, sodium bicarbonate in an amount of about 0.2 mEq to 5 mEq per 2 mg of omeprazole, and at least one thickening agent, wherein the composition is in a form of a powder for suspension that is storage stable at room temperature; and wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml at any time within about 20 minutes after administration.

Claim 295. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml at any time within about 15 minutes after administration.

Claim 296. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml at any time within about 10 minutes after administration.

Claim 297. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.2 µg/ml at any time within about 15 minutes after administration.

Claim 298. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 6 hours after administration.

Claim 299. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.15 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 1.5 hours after administration.

Claim 300. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} within about 1 hour after administration.

Claim 301. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} within about 30 minutes after administration.

Claim 302. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} within about 45 minutes after administration.

Claim 303. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} within about 15 minutes to about 45 minutes after administration.

Claim 304. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average C_{\max} of the proton pump inhibitor of about 1.0 µg/ml.

Claim 305. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average C_{\max} of the proton pump inhibitor of between about 0.5 µg/ml to about 1.7 µg/ml after administration.

Claim 306. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of greater than about 1.0 µg/ml at any time within about 20 minutes after administration.

Claim 307. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of greater than about 1.0 µg/ml at any time within about 40 minutes after administration.

Claim 308. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average C_{\max} of the omeprazole of between about 0.5 µg/ml and 1.7 µg/ml at any time within about 45 minutes after administration.

Claim 309. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of between about 0.3 µg/ml and 1.2 µg/ml at any time within about 10 minutes after administration.

Claim 310. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of between about 0.5 µg/ml and about 1.6 µg/ml at any time within about 15 minutes after administration.

Claim 311. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.4 µg/ml at any time within about 20 minutes after administration.

Claim 312. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of between about 0.7 µg/ml and 1.2 µg/ml at any time within about 30 minutes after administration.

Claim 313. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average plasma concentration of the omeprazole is determined from about 15 subjects.

Claim 314. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average plasma concentration of the omeprazole is determined from about 15 adult human subjects and is at least about 0.4 µg/ml at any time within about 30 minutes after administration.

Claim 315. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average plasma concentration of omeprazole is determined from about 10 adult human subjects and is at least about 0.7 µg/ml at any time within about 30 minutes after administration.

Claim 316. (New) The composition of claim 294, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average plasma concentration of the omeprazole is determined from about 10 adult human subjects and is at least about 0.4 µg/ml at any time within about 15 minutes after administration.

Claim 317. (New) The composition of claim 294, wherein the composition comprises 40 mg of omeprazole and wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average C_{\max} is about 1.0 µg/ml.

Claim 318. (New) A pharmaceutical composition comprising:

- (a) active ingredients consisting essentially of:
 - (i) about 20 mg to about 40 mg non-enteric coated omeprazole, and
 - (ii) sodium bicarbonate; and
- (b) at least one thickening agent,

wherein the composition is a dry powder for suspension and wherein after mixing the powder in water, the concentration of the sodium bicarbonate is approximately 5 percent to approximately 60 percent weight to weight in the resulting suspension.

Claim 319. (New) The pharmaceutical composition of claim 318, wherein the omeprazole is present in an amount of about 20 mg

Claim 320. (New) The pharmaceutical composition of claim 318, wherein the omeprazole is present in an amount of about 40 mg.

Claim 321. (New) The pharmaceutical composition of claim 319, wherein the concentration of sodium bicarbonate is approximately 5 percent.

Claim 322. (New) The pharmaceutical composition of claim 319, wherein the concentration of sodium bicarbonate is approximately 7.5 percent to approximately 10 percent.

Claim 323. (New) The pharmaceutical composition of claim 319, wherein the concentration of sodium bicarbonate is approximately 8.4 percent.

Claim 324. (New) The pharmaceutical composition of claim 319, wherein the concentration of sodium bicarbonate is approximately 10 percent.

Claim 325. (New) The pharmaceutical composition of claim 320, wherein the concentration of sodium bicarbonate is approximately 5 percent.

Claim 326. (New) The pharmaceutical composition of claim 320, wherein the concentration of sodium bicarbonate is approximately 7.5 percent to approximately 10 percent.

Claim 327. (New) The pharmaceutical composition of claim 320, wherein the concentration of sodium bicarbonate is approximately 8.4 percent.

Claim 328. (New) The pharmaceutical composition of claim 320, wherein the concentration of sodium bicarbonate is approximately 10 percent.